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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,575	04/14/2000	FRANCIS JAMES ROURKE	7042-R	9622

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EXAMINER

ANDERSON, CATHARINE L

ART UNIT PAPER NUMBER

3761

DATE MAILED: 12/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/529,575

Applicant(s)

ROURKE ET AL.

Examiner

C. Lynne Anderson

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 31-33, 36, 41-46 and 48-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-33, 36, 41-46 and 48-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 September 2003 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-33, 36, 41-46, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cadwell (5,874,164).

With respect to claims 31, 32, 33, and 36, Cadwell discloses all aspects of the claimed invention but remains silent as to the percent by weight of the protease inhibitor. Cadwell discloses an absorbent article, as described in column 6, lines 23-26, at least a portion of which comprises a protease inhibitor, as described in column 55, lines 16-19. The protease inhibitor is pentamidine, as described in column 55, line 28, which has an IC<sub>50</sub> of about 500  $\mu$ M or less, no more than 100  $\mu$ M, and produces at least a 10% reduction in substrate hydrolysis by a protease.

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It would have been obvious to one of ordinary skill in the art at the time of invention to have protease inhibitor present in the amounts of between about 0.0001% and about 30% by weight, since it has been held that where the general conditions of a claim (i.e. the presence of protease inhibitor in some amount) are disclosed in the art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 41, the article comprises a delivery system, a barrier web 15, as shown in figure 8, which comprises the protease inhibitor.

With respect to claims 42 and 43, the article can comprise a delivery system, a bandage or surgical gauze, as disclosed in column 53, lines 57-62, which facilitates the healing of a wounds and is therefore a skin care composition. The skin care composition comprises between about 0.0001% and about 30% of the protease inhibitor, as disclosed in the rejection of claim 31 above.

With respect to claim 44, the delivery system is a solid support.

With respect to claim 45, the delivery system is activatable by moisture and releases the protease inhibitor, as disclosed in column 55, lines 31-35.

With respect to claim 46, the delivery system contains the protease inhibitor as molecules, or particles, as disclosed in column 55, line 37.

With respect to claim 48, the article comprises a barrier web 15, as shown in figure 8, having the protease inhibitor disposed on at least a portion thereof. The barrier web 15 comes in contact with the wearer.

With respect to claim 49, the barrier web 15 is part of the waist region of the article, as shown in figure 7.

With respect to claims 50 and 51, the wearer-contacting surface may be a bandage or surgical gauze, as disclosed in column 53, lines 57-62, which is a topsheet.

With respect to claims 52 and 53, it would have been an obvious matter of design choice for the topsheet to comprise regions that do not contain the skin care composition and have the skin care composition disposed in a plurality of stripes, since the applicant has not shown that this application of the skin care composition solves any stated problem or serves any particular purpose, and it appears the invention would perform equally well with the skin care composition disposed on all regions of the topsheet.

### ***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,928,174 pertains to an article comprising pentamidine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (703) 306-5716. The examiner can normally be reached on Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

*WLA*  
cla

December 15, 2003



WEILUN LO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700